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110TH CONGRESS
1ST SESSION

H. R. 3368

To amend the Public Health Service Act to establish a pulmonary hypertension clinical research network, to expand pulmonary hypertension research and training, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 3, 2007

Mr. LANTOS (for himself and Mr. BRADY of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Public Health Service Act to establish a pulmonary hypertension clinical research network, to expand pulmonary hypertension research and training, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pulmonary Hypertension Research and Education Act of 2007''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Pulmonary hypertension is a serious and often fatal condition where the blood pressure in the lungs rises to dangerously high levels. In pulmonary hypertension patients, the walls of the arteries that take blood from the right side of the heart to the lungs thicken and constrict. As a result, the right side of the heart has to pump harder to move blood into the lungs, causing it to enlarge and ultimately fail.

(2) In order to take full advantage of the tremendous potential for finding a cure or effective treatment, the Federal investment in pulmonary hypertension must be expanded, and collaboration among top pulmonary hypertension research centers must be increased.

(3) Pulmonary hypertension remains a difficult diagnosis and is rarely picked up in a routine medical examination. Even in its later stages, the signs of the disease can be confused with other conditions affecting the heart and lungs. The use of new diagnostic standards has been positively related to the rates of diagnosis.

(4) In the more advanced stages of pulmonary hypertension, the patient is able to perform only minimal activity and has symptoms even when rest-

ing, resulting in considerable disability. The disease may worsen to the point where the patient is completely bedridden.

(5) In 1981, the National Heart, Lung, and Blood Institute established the first pulmonary hypertension patient registry in the world. The registry followed 194 people with pulmonary hypertension over a period of at least one year and, in some cases, more than seven years. Much of what is known about the illness today stems from this study.

(6) Because the cause of pulmonary hypertension is still not fully understood and there is still not a cure for pulmonary hypertension, basic research studies are focusing on the possible involvement of immunologic and genetic factors in the cause and progression of pulmonary hypertension, looking at agents that cause narrowing of the pulmonary blood vessels, and identifying factors that cause growth of endothelial and smooth muscle cells, and formation of scar tissue in the vessel walls.

(7) As research progresses, so do treatments for pulmonary hypertension. Currently, there are six FDA-approved medications for pulmonary hypertension and several more in trials. However, not all medications are effective in all patients. In addition,

all pulmonary hypertension treatments have significant negative side effects that impact patients' quality of life. Lung transplantation is often considered a treatment of last resort for pulmonary hypertension.

(8) The number of physicians who treat pulmonary hypertension, and the number of pulmonary hypertension patients receiving treatment, has grown exponentially over the past decade, leading to the need for increased education of medical professionals. In 2001, there were 100 identified physicians treating pulmonary hypertension, and 3,000 patients receiving treatment. In 2006, there were an estimated 3,000 such physicians and 30,000 such patients. While pulmonary hypertension treatment now includes the option of relatively easy to administer oral therapies, effective management of pulmonary hypertension remains complicated. Given the increase in the number of physicians treating pulmonary hypertension, education of medical professionals about pulmonary hypertension management is critical to ensure optimal patient care.

(9) In December 2006, the National Heart, Lung, and Blood Institute hosted a landmark meeting of pulmonary hypertension researchers and clini-

cians throughout the world. Over 500 individuals attended, making this the largest such meeting organized by a Federal department for this disease. During the meeting, there was clear consensus that communication among researchers is key to future advancement in the fight against this devastating and expensive disease.

SEC. 3. PULMONARY HYPERTENSION CLINICAL RESEARCH NETWORK; EXPANSION OF PULMONARY HYPERTENSION RESEARCH AND TRAINING.

Subpart 2 of part C of title IV of the Public Health Service Act (42 U.S.C. 285b et seq.) is amended by inserting after section 424B the following section:

''PULMONARY HYPERTENSION

''SEC. 424C.

''(a) IN GENERAL.—The Director of the Institute shall expand, intensify, and coordinate the activities of the Institute with respect to research on pulmonary hypertension.

''(b) ESTABLISHMENT OF PULMONARY HYPERTENSION CLINICAL RESEARCH NETWORK.—

''(1) Not later than one year after the date of the enactment of this section, the Director of the Institute shall establish a Pulmonary Hypertension Clinical Research Network (in this section referred to as the 'network'). The purpose of the network

shall be to conduct multiple clinical trials to evaluate new treatment approaches for pulmonary hypertension and facilitate collaboration among investigators with expertise in pulmonary hypertension. The network shall consist of the following:

"(A) No fewer than 15 clinical centers designated by the Director.

"(B) An institute project scientist, as defined and appointed by the Director.

"(C) A data and coordinating center, as defined and appointed by the Director.

"(D) A data and safety monitoring board, as defined and appointed by the Director.

"(E) A steering committee comprised of the principal investigators from each clinical center described under subparagraph (A), the data and coordinating center described in subparagraph (C), and the institute project scientist described in subparagraph (B).

"(F) An independent protocol review committee, as defined and appointed by the Director.

"(2) STEERING COMMITTEE.—The steering committee described in paragraph (1)(E) shall determine the specific clinical trials to be performed

under this section, establish standards for subject selection and characterization for such trials, develop detailed protocols for such trials, and analyze and publish the results of such trials. Possible clinical trials shall include:

"(A) Combination therapies for pulmonary hypertension.

"(B) New avenues of drug therapy based on recognized cellular defects in pulmonary hypertension that are not impacted by current treatment.

"(C) Use of endothelial progenitor cells for replacement of abnormal pulmonary vascular cells in pulmonary hypertension.

"(D) Discovery of treatment effects which are most predictive of long-term outcome.

"(3) PROGRAM MANAGEMENT; APPOINTMENTS.—

"(A) IN GENERAL.—The Institute shall be responsible for organizing and providing support for the network.

"(B) INSTITUTE PROJECT SCIENTIST.—The institute project scientist appointed under paragraph (1)(B) shall—

"(i) monitor the recruitment of subjects for the trials and the progress of the trials;

"(ii) ensure disclosure of conflicts of interest and adherence of the conduct of the clinical trials to the policies of the Institute; and

"(iii) conduct, with the institute grants management specialist described in subparagraph (C), the fiscal management of the network.

"(C) INSTITUTE MANAGEMENT SPECIALIST.—An institute grants management specialist (as defined and appointed by the Director) shall assist the institute project scientist in conducting the fiscal management of the network under subparagraph (B)(iii).

"(D) ADDITIONAL APPOINTMENTS.—The Director shall appoint the Chair of the steering committee described in paragraph (1)(E) and all members of the protocol review committee under paragraph (1)(F) and the data safety monitoring board under paragraph (1)(D).

"(e) PULMONARY HYPERTENSION PRECEPTORSHIP AND TRAINING PROGRAM.—

''(1) IN GENERAL.—Not later than one year after the date of the enactment of this section, the Director of the Institute shall carry out a grant program under which the Director makes a grant to (or enters into a contract with) a national nonprofit entity with expertise in pulmonary hypertension to establish and administer a national Pulmonary Hypertension Preceptorship and Training Program (in this section referred to as the 'program').

''(2) PURPOSE.—The program shall facilitate the direct education and training of medical professionals (including cardiologists, pulmonologists, rheumatologists, and primary care physicians) by experienced pulmonary hypertension specialists in clinical settings. The purpose of the program is to increase the number of physicians in the United States trained to effectively diagnosis, treat, and manage pulmonary hypertension.

''(3) REGIONAL TRAINING SITES.—To carry out the purpose of the program described in paragraph (2), the entity awarded the grant (or contract) under paragraph (1) shall under the program facilitate the creation of no fewer than five regional training sites across the United States at academic health centers,

hospitals, or private medical practices recognized for their expertise in pulmonary hypertension.

''(4) REGIONAL SITE CONTACTS.—Under the program—

''(A) each regional training site shall identify a site contact; and

''(B) the Director shall specify a percentage of the grant funds required to be allocated for purposes of providing each such site contact with a stipend.

''(5) PARTICIPANT RECRUITMENT AND PROGRAM GUIDELINES.—The nonprofit entity awarded the grant (or contract) under paragraph (1) shall establish mechanisms for identifying and enrolling interested health professionals in the program. The nonprofit entity shall also work with the regional training sites under paragraph (3) and the Institute to establish model guidelines for the program.

''(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2009 through 2012.''.

SEC. 4. INCREASING PUBLIC AWARENESS OF PULMONARY HYPERTENSION.

(a) PULMONARY HYPERTENSION EDUCATION PROGRAM.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, shall develop and disseminate to the public information regarding pulmonary hypertension, including materials on—

(1) basic information on pulmonary hypertension and its symptoms;

(2) the incidence and prevalence of pulmonary hypertension;

(3) diseases and conditions that can lead to pulmonary hypertension as a secondary diagnosis;

(4) the importance of early diagnosis; and

(5) the availability, as medically appropriate, of a range of treatment options and pulmonary hypertension.

(b) DISSEMINATION OF INFORMATION.—The Secretary of Health and Human Services shall disseminate information under subsection (a) through arrangements with a national non-profit entity with expertise in pulmonary hypertension.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized

to be appropriated such sums as may be necessary for each of the fiscal years 2009 through 2012.

SEC. 5. DISSEMINATION OF INFORMATION TO HEALTH PROFESSIONALS ON PULMONARY HYPERTENSION.

(a) DISSEMINATION OF INFORMATION.—The Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration and the Director of the Centers for Disease Control and Prevention, shall develop and disseminate to health care providers information on pulmonary hypertension for the purpose of ensuring that providers remain informed about the disease, its presenting symptoms, and current treatment options. Such information shall include material on the warning signs of pulmonary hypertension, the importance of early diagnosis, diagnostic criteria, and therapies approved by the Food and Drug Administration for the disease. Such health care providers shall include cardiologists, pulmonologists, rheumatologists, primary care physicians, pediatricians, and nurse practitioners.

(b) DISSEMINATION OF INFORMATION.—The Secretary of Health and Human Services shall disseminate information under subsection (a) through arrangements with a national non-profit entity with expertise in pulmonary hypertension.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2009 through 2012.

SEC. 6 STUDY BY GOVERNMENT ACCOUNTABILITY OFFICE ON MEDICARE AND MEDICAID COVERAGE STANDARDS.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study on the coverage standards that, under the Medicare program under title XVIII of the Social Security Act and the Medicaid program under title XIX of such Act, apply to individuals with pulmonary hypertension. The study shall detail coverage standards under such programs for all therapies approved by the Food and Drug Administration for the treatment of pulmonary hypertension. The study shall take into account appropriate outpatient or home health care delivery settings for delivery of such services.

(b) REPORT.—Not later than six months after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report describing the findings of the study under subsection (a).

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